

Appendix 1

Letter of Invitation

I would like to invite you to take part in a research study on the role of vitamin D in relation to glucose control. The study is a collaboration between Exercise Scientists in the Department of Sport and Exercise Science, Aberystwyth University and medical staff within the Hywel Dda local health board who have a joint interest in understanding the relationships between lifestyle and diabetes.

First of all I would like to thank you for taking the time to read this information. Before you decide if you would like to be involved it is important that you understand that participation is voluntary and will not influence your treatment by the health service in any way. Below I have given some very brief details on why the research is being done and what would be required from you if you were to take part. I would be happy to provide you with more information, my contact details can be found at the end of this letter along with an expression of interest form and return envelope. If you are interested in becoming involved in the research study please return this form or contact one of the research team by email or telephone, we will then arrange an opportunity for you to come in and discuss the study and what is involved in detail. You will not be committing to take part in the study and you can withdraw at any time which having to give a reason.

We get vitamin D from both the food we eat and directly from exposure to the sun and there is some evidence to suggest that vitamin D deficiency may be linked to the development of type 2 diabetes. To explore this further we will examine vitamin D levels in various groups of people, some with diabetes and some without. If you take part in the study you would be required to attend the Department of Sport and Exercise Science once every 6 months over a one year period where we would take a blood sample, and you would be asked to complete some lifestyle questionnaires. Research into the role of vitamin D in relation to glucose control may help those with pre-existing diabetes manage their illness and reduce the need for medications in the future. It may also help prevent the development of the disease in healthy people and those with impaired glucose tolerance.

Take your time to decide whether or not you wish to find out more about the study. If you feel you would like to take part in the research, or would simply like more information please contact me by phone on 01970 622070 or by email fic7@aber.ac.uk alternately you can complete the expression of interest form and return it to me in the envelope provided.

Kind Regards

Ffion Curtis

Tel: 01970 622070

Email: fic7@aber.ac.uk

Declaration of Interest

The Effect of Vitamin D and Physical Activity on Glucose Control

Name: _____

Date of Birth: _____

Telephone: _____

Email: _____

Address: _____

Llythyr o Wahoddiad

Hoffwn eich gwahodd i gymryd rhan mewn astudiaeth ymchwil ar rôl Fitamin D yn diabetes, math 2. Astudiaeth ar y cyd ydyw rhwng Gwyddonwyr Ymarfer Corff yn Adran Gwyddor Chwaraeon ac Ymarfer Corff, Prifysgol Aberystwyth a staff meddygol bwrdd iechyd lleol Hywel Dda sydd â diddordeb cyffredin mewn deall y berthynas rhwng ffordd o fyw a diabetes.

Yn gyntaf, hoffwn ddiolch i chi am gymryd yr amser i ddarllen yr wybodaeth yma. Cyn ichi benderfynu a hoffech gymryd rhan, mae'n bwysig ichi ddeall mai dewis cymryd rhan a fydddech ac na fyddai gwneud hynny yn dylanwadu ar eich triniaeth gan y gwasanaeth iechyd mewn unrhyw ffordd. Nodaf isod fanylion cryno iawn am y rhesymau dros wneud y gwaith ymchwil a'r hyn y byddem yn ei ddisgwyl gennych pe baech yn cymryd rhan. Byddwn yn barod i roi mwy o wybodaeth i chi, a gellir dod o hyd i'm manylion cyswllt ar ddiwedd y llythyr hwn, ynghyd â ffurflen yn mynegi diddordeb ac amlen i'w dychwelyd ynddi. Os oes gennych ddiddordeb mewn cymryd rhan yn yr astudiaeth ymchwil, dychwelwch y ffurflen hon neu cysylltwch ag un o'r tîm ymchwil drwy e-bost neu ffôn, ac fe wnawn ni drefnu adeg ichi ddod atom i drafod yr astudiaeth a'r hyn y mae'n ei olygu mewn mwy o fanylder. Ni fyddwch yn ymrwymo i gymryd rhan yn yr astudiaeth ac fe ellwch dynnu'n ôl ar unrhyw adeg heb roi reswm.

Daw fitamin D o'r bwyd yr ydym yn ei fwyta ac yn uniongyrchol drwy ddod i gysylltiad â'r haul a cheir peth tystiolaeth i awgrymu bod modd cysylltu diffyg fitamin D â datblygiad diabetes math 2. Er mwyn archwilio hyn ymhellach, byddwn yn archwilio lefelau fitamin D grwpiau amrywiol o bobl, rhai ohonynt yn dioddef o diabetes a rhai ohonynt ddim. Pe baech yn cymryd rhan yn yr astudiaeth, byddai gofyn ichi ddod i'r Adran Gwyddor Chwaraeon ac Ymarfer Corff unwaith bob 6 mis yn ystod cyfnod o flwyddyn lle byddem yn cymryd sampl o'ch gwaed ac yn gofyn ichi gwblhau rhai holiaduron ynghylch eich ffordd o fyw. Mae'n bosibl y bydd ymchwil i rôl fitamin D mewn perthynas â diabetes o gymorth i'r rheiny sydd eisoes yn dioddef o diabetes reoli eu salwch a lleihau'r angen am feddyginiaeth yn y dyfodol. Mae'n bosibl y bydd hefyd yn rhwystro datblygiad y cyflwr mewn pobl iach a'r rheiny â goddefiad diffygol i glwcos.

Cymrwch eich amser i benderfynu a hoffech wybod mwy am yr astudiaeth ai peidio. Os hoffech gymryd rhan yn yr ymchwil, neu os hoffech fwy o wybodaeth, cysylltwch â mi drwy ffonio 01970 622070 neu drwy anfon e-bost at fic7@aber.ac.uk neu fel arall, gellwch gwblhau'r ffurflen yn mynegi diddordeb a'i dychwelyd ataf yn yr amlen a ddarperir.

Cofion Gorau

Ffion Curtis

Ffôn: 01970 622070

E-bost: fic7@aber.ac.uk

Datganiad o Ddiddordeb

Rôl Fitamin D a Gweithgarwch Corfforol yn Diabetes, Math 2

Enw: _____

Dyddiad Geni: _____

Ffôn: _____

E-bost: _____

Cyfeiriad: _____

Department for Sport and Exercise Science

Carwyn James Building, Penglais Campus, Aberystwyth University, SY23 3FD

Principal Investigator: Ffion Curtis (ffc7@aber.ac.uk; 01970 622070)
Supervisors: Dr Rhys Thatcher (ryt@aber.ac.uk; 01970 628 630)
Dr Glen Davison (gdd@aber.ac.uk; 01970 628425)

Study Title: The Role of Vitamin D and Physical Activity in Type 2 Diabetes

Invitation:

You are invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

What is the purpose of this study?

The purpose of this study is to investigate the relationship between diabetes and vitamin D. Improving our understanding of this relationship can inform treatment with the aim of reducing the need for medications for the treatment of diabetes. It will form part of a PhD thesis that will examine this relationship in more depth.

Why have I been invited?

You have been invited to take part in the research because you have either been identified by your General Practitioner to fit the criteria of having type-2 diabetes or impaired glucose tolerance, or you can be part of a non-diabetic comparison group. For this research we are recruiting 50 people with type-2 diabetes, 50 people with impaired glucose tolerance and 50 people without diabetes.

Do I have to take part?

No. It's up to you to decide whether or not to take part. If you decide that you wish to be involved, we will ask you to sign a consent form, which will be witnessed by someone not involved in the study.

You are still free to withdraw from the study at any time and without giving a reason. If you wish to withdraw from the study all we ask is that you let us know by contacting the Sport and Exercise Science Department, Aberystwyth University (01970 622 070) and ask to speak to Ffion Curtis.

If you are unhappy with anything during your participation you can write to: The secretary of the Aberystwyth University Ethics Committee for Research Procedures, Deans' Office, Cledwyn Building, Aberystwyth University.

What will I have to do?

Everybody who takes part in the study will be asked to attend the Department of Sport and Exercise Science in Aberystwyth University once every six months over a 12 month period. A blood sample will be taken to measure your glucose, insulin and vitamin D levels, you will also be asked to complete three lifestyle questionnaires.

In addition, 25 people from each of the three groups (diabetic, impaired glucose tolerance and non-diabetics) who take part in the study will be asked to attend the Department for an additional visit on each of the three occasions. During this

additional visit you would be asked to cycle at a moderate pace on an exercise bike for ten to fifteen minutes throughout which your heart rate would be monitored. You would also be provided with scales and instructions on how to record your food intake for a three day period to provide detailed dietary information.

How long will each visit take?

Each visit will take about an hour. So in total over a twelve month period your time commitment would be three hours, unless you are part of the group attending for the additional visit, in which case it would be six hours.

How will I know if I will be asked to attend for the additional hour on each occasion?

Those who attend twice will be randomly selected to do so; you have a 50% chance of being put in either group.

Are there any risks?

With all exercise there are risks, however for the purpose of this study the exercise you will be asked to do will require little effort (i.e. light to moderate intensity), for which the risk is minimal. There is also a small risk of infection and/or bruising after the blood sample being taken. However this risk is small as we carefully follow standard procedures to ensure your safety, and all staff will be fully trained to take blood.

What are the benefits of taking part?

Research into the role of vitamin D in relation to diabetes may help those with pre-existing diabetes manage their illness and reduce the need for medications. As an individual this research will provide us with information about your vitamin D and fitness levels.

What happens at the end of the study?

The information collected during the study will be written up as part of a PhD thesis and as scientific papers. The results gained may be used in other research studies however your personal details will not be published and all data will be anonymous.

Will my taking part in the study be kept confidential?

All information provided or obtained will be treated with utmost confidentiality, and no information that could lead to your identity will be disclosed in any reports on the project, or to any other party. All data collected will be stored securely for an indefinite period of time with a minimum of 6 years for use in research publications; however any data published will be kept anonymous. The data collected may also be used in further research projects and/or by other researchers which have ethical approval.

Involvement of the General Practitioner (GP)

Your GP's involvement in this study is to refer you to the study if you meet the requirements for taking part. However, if we uncover any other issues as part of your undertaking this study we would request your permission to forward the details to your GP. We would also advise you to make an appointment to see your GP.

Will participation affect my treatment by the Health Service?

No. Your involvement in this study will not affect your existing, or future, treatment by the NHS in any way.

Will I be able to claim travel expenses?

Unfortunately we are unable to offer any money to cover travel expenses, however the Department where testing will be taking place is only a ten minute walk from Aberystwyth town centre. It is also on a regular bus route and there are car parking areas on the University campus.

Questions?

If you have a concern about any aspect of this study, please feel free to contact one of the researchers Dr Rhys Thatcher, Dr Glen Davison or Miss Ffion Curtis, whose contact details can be seen at the top of this sheet

Statement of Informed Consent:

I have read the description of the testing procedures involved in this study on the 'The role of vitamin D and physical activity in type 2 diabetes' and I understand what will be required of me as a participant. I have been given the opportunity to ask questions to clarify any aspect of the procedures and I am aware that I have the right to withdraw from the study at any time with no obligation to provide reasons for my decision. I also understand that if I have any unusual test results my GP will be informed.

**I agree to take part in the
'The role of vitamin D and physical activity in type 2 diabetes' study.**

Name(please print): _____ Date: _____

Signature: _____ D.o.B. _____

Witnessed By:

Name (please print): _____ Signature: _____

If you have any queries do not hesitate to ask questions. We can be contacted the Aberystwyth University on tel: 01970 622070 Email: fic@aber.ac.uk
All issues related to indemnity are addressed by Aberystwyth University's insurance cover.

Adran Gwyddor Chwaraeon ac Ymarfer Corff

Adeilad Carwyn James, Campws Penglais, Prifysgol Aberystwyth, SY23 3FD

Prif Ymchwilydd: Ffion Curtis (fic7@aber.ac.uk; 01970 622070)

Arolygwyr: Dr Rhys Thatcher (ryt@aber.ac.uk; 01970 628 630)

Dr Glen Davison (gdd@aber.ac.uk; 01970 628425)

Teitl yr Astudiaeth: Rôl Fitamin D a Gweithgaredd Corfforol yn achos Clefyd Siwgr Math 2

Gwahoddiad:

Fe'ch gwahoddir i gymryd rhan mewn astudiaeth ymchwil. Cyn i chi wneud unrhyw benderfyniadau, mae'n bwysig i chi ddeall pam y mae'r astudiaeth yn cael ei gwneud a'r hyn y mae'n ei olygu. Cymerwch amser i ddarllen yr wybodaeth ganlynol yn ofalus.

Beth yw diben yr astudiaeth hon?

Diben yr astudiaeth hon yw archwilio'r berthynas rhwng clefyd siwgr a fitamin D. Gall gwella ein dealltwriaeth o'r berthynas hon ddylanwadu ar driniaeth gyda'r nod o leihau'r angen am foddion i drin y clefyd. Bydd yn ffurfio rhan o draethawd ymchwil PhD a fydd yn archwilio'r berthynas hon yn fwy trwyadl.

Pam fy mod i wedi cael gwahoddiad?

Rydych wedi cael eich gwahodd i gymryd rhan yn yr ymchwil oherwydd bod eich Meddyg Teulu wedi nodi eich bod naill ai'n dioddef o glefyd siwgr math 2 neu o oddefiad glwcos diffygiol, neu fe allwch fod yn rhan o'r grŵp cymharu nad ydyn nhw'n dioddef o'r clefyd siwgr. At ddibenion yr ymchwil hwn, rydym yn recriwtio 50 o bobl gyda chlefyd siwgr math 2, 50 o bobl gyda goddefiad glwcos diffygiol, a 50 o bobl nad ydyn nhw'n dioddef o glefyd siwgr.

A oes raid i mi gymryd rhan?

Nac oes. Mae hi i fyny i chi os ydych eisiau cymryd rhan neu beidio. Os ydych eisiau cymryd rhan, byddwn yn gofyn i chi arwyddo ffurflen caniatâd, a hynny yng ngŵydd tyst na fydd yn cymryd rhan yn yr astudiaeth.

Rydych yn dal yn rhydd i dynnu'n ôl o'r astudiaeth ar unrhyw adeg, a hynny heb orfod rhoi rheswm. Os ydych yn dymuno gwneud hynny, y cyfan yr ydym yn gofyn i chi ei wneud yw rhoi gwybod inni drwy gysylltu â'r Adran Gwyddor Chwaraeon ac Ymarfer Corff, Prifysgol Aberystwyth (01970 622 070) a gofyn am gael siarad â Ffion Curtis.

Os ydych yn anhapus ag unrhyw beth pan fyddwch yn cymryd rhan, gallwch ysgrifennu at: Ysgrifennydd Pwyllgor Moeseg Dulliau Ymchwil Prifysgol Aberystwyth, Swyddfa'r Deon, Adeilad Cledwyn, Prifysgol Aberystwyth.

Beth fydd yn rhaid i mi ei wneud?

Gofynnir i bawb sy'n cymryd rhan ddod i'r Adran Gwyddor Chwaraeon ac Ymarfer Corff ym Mhrifysgol Aberystwyth unwaith bob chwe mis dros gyfnod o 12 mis, h.y. tri ymweliad, a phob un ohonynt yn para tuag awr. Bydd sampl gwaed yn cael ei gymryd oddi wrthy ch er mwyn mesur eich lefelau glwcos, inswlin a fitamin D, a gofynnir hefyd i chi gwblhau tri holiadur ar eich ffordd o fyw.

Hefyd, gofynnir i 25 o bobl o bob un o'r tir grŵp (diabetig, goddefiad glwcos diffygiol a'r rhai nad ydynt yn ddiabetig) ddod i'r Adran am awr ychwanegol ar bob un o'r tir achlysur. Yn ystod yr ymweliad ychwanegol hwn, gofynnir i chi feicio ar gyflymder cymhedrol ar feic ymarfer am ddeg i bymtheng munud tra bydd cyfradd eich calon yn cael ei fonitro. Hefyd, byddwch yn derbyn clorian a chyfarwyddyd ar sut i recordio'r bwyd a fwyteu dros gyfnod o dri diwrnod er mwyn darparu gwybodaeth ddietegol fanwl.

Sut fyddai'n gwybod os bydd rhaid i mi fod yn bresennol am awr yn ychwanegol ar bob achlysur?

Bydd y rheini sy'n gorfod dod i'r adran ddwywaith wedi eu dewis i wneud hynny ar hap; felly, mae gennych siawns o 50% o gael eich rhoi yn y naill grŵp neu'r llall.

A oes unrhyw beryglon?

Mae peryglon ynghlwm wrth unrhyw fath o ymarfer corff. Serch hynny, bydd yr ymarfer corff y gofynnir i chi ei wneud at ddibenion yr astudiaeth hon yn gymhedrol, sy'n golygu nad oes fawr ddim perygl. Hefyd, mae heintio yn risg posibl, ond bychan iawn, wrth dynnu gwaed. Mae'r risg hwn yn fychan gan y byddwn yn dilyn dulliau safonol tynnu gwaed yn ofalus iawn er mwyn sicrhau eich bod yn ddiogel, ac y mae'r staff sy'n ymwneud â'r astudiaeth wedi eu hyfforddi i dynnu gwaed.

Beth yw manteision cymryd rhan yn y fath astudiaeth?

Mae'n bosibl y gall ymchwil i rôl fitamin D mewn perthynas â chlefyd siwgr helpu'r rheini sy'n dioddef o'r clefyd i'w reoli a lleihau'r angen am feddyginiaethau. Hefyd, bydd yr ymchwil hwn yn rhoi gwybodaeth inni am eich lefelau ffitrwydd a fitamin D.

Beth sy'n digwydd ar ddiwedd yr astudiaeth?

Bydd yr wybodaeth a gesglir yn ystod yr astudiaeth yn cael ei gynnwys mewn traethawd PhD a'i gyflwyno mewn papurau gwyddonol. Dichon y bydd y canlyniadau'n cael eu defnyddio mewn astudiaethau ymchwil eraill. Serch hynny, ni chyhoeddir eich manylion personol, a bydd yr holl ddata yn anhysbys.

A fydd y ffaith fy mod yn cymryd rhan yn cael ei gadw'n gyfrinachol?

Bydd yr holl wybodaeth a ddarperir neu a dderbynnir yn cael ei drin yn gwbl gyfrinachol, ac ni fydd unrhyw wybodaeth a allai ddatgelu pwy ydych yn cael ei ddadlennu mewn unrhyw adroddiadau ar y prosiect, nac ychwaith i unrhyw berson arall. Bydd yr holl ddata a gesglir yn cael ei gadw'n ddiogel am gyfnod amhenodol, gyda lleiafswm o chwe blynedd, cyn y ceir ei ddefnyddio mewn cyhoeddiadau ymchwil; fodd bynnag, bydd unrhyw ddata a gyhoeddir yn cael ei gadw'n ddienw. Ar ben hynny, mae'n bosibl y bydd y data a gesglir yn cael ei ddefnyddio mewn prosiectau ymchwil pellach a/neu gan ymchwilwyr eraill sydd wedi cael sêl bendith foesegol i wneud hynny.

Rhan y meddyg teulu yn yr astudiaeth

Unig ran y meddyg teulu yn yr astudiaeth hon yw eich cyfeirio at yr astudiaeth os ydych yn cwrdd â'r gofynion i gymryd rhan. Fodd bynnag, os ydym yn darganfod unrhyw broblemau iechyd eraill wrth i chi gymryd rhan yn yr astudiaeth, fe fyddwn yn hysbysu eich meddyg teulu ynghylch hynny.

A fydd cymryd rhan yn effeithio fy nhriniaeth o dan y Gwasanaeth Iechyd?

Na. Ni fydd cymryd rhan yn yr astudiaeth hon yn cael effaith ar eich triniaeth bresennol, na'ch triniaeth yn y dyfodol, o dan y Gwasanaeth Iechyd.

Unrhyw gwestiynau?

Os oes gennych unrhyw bryderon ynghylch unrhyw agwedd o'r astudiaeth hon, y mae croeso i chi gysylltu ag un o'n hymchwilwyr, sef Dr Rhys Thatcher, Dr Glen Davison neu Miss Ffion Curtis. Mae eu manylion cyswllt ar frig y daflen hon.

Datganiad o Gydsyniad Gwybodus:

Rwyf wedi darllen y disgrifiad o'r dulliau profi a oblygir gan yr astudiaeth hon ar 'Rôl fitamin D a gweithgaredd corfforol yn achos clefyd siwgr math 2', ac rwyf yn deall beth a ddisgwylir gennyf fel cyfranogwr. Rhoddwyd cyfle i mi ofyn cwestiynau i egluro unrhyw agwedd ar y dulliau gweithredu ac rwyf yn ymwybodol fod gennyf yr hawl i dynnu'n ôl o'r astudiaeth ar unrhyw adeg heb unrhyw orfodaeth i roi rhesymau am fy mhenderfyniad.

Rwy'n cytuno i gymryd rhan yn yr astudiaeth ar

'Rôl fitamin D a gweithgaredd corfforol yn achos clefyd siwgr math 2'

Enw (llythrennau bras):	_____	Dyddiad:	_____
Llofnod:	_____	Dyddiad geni:	_____
Ardystiwyd gan:			
Enw (llythrennau bras):	_____	Llofnod:	_____

Os oes gennych unrhyw gwestiynau, cysylltwch â ni. Gallwch gysylltu â ni drwy Brifysgol Aberystwyth ar: 01970 622070, E-bost: fic@aber.ac.uk

**ABERYSTWYTH UNIVERSITY
DEPARTMENT OF SPORT AND EXERCISE SCIENCE
PARTICIPANT INFORMATION**

Carwyn James Building, Penglais Campus, Aberystwyth University, SY23 3FD

Principal Investigator: Ffion Curtis (fic7@aber.ac.uk; 01970 622070)

Supervisors: Dr Rhys Thatcher (ryt@aber.ac.uk; 01970 628 630)

Dr Glen Davison (gdd@aber.ac.uk; 01970 628425)

Study title: The effect of vitamin D and Physical Activity on Glucose Control

Background

Whilst we get some vitamin D from our diet it is primarily obtained from exposure to sunlight. As a consequence of industrialisation and changing lifestyles vitamin D deficiency is now a growing health concern. Vitamin D deficiency has been linked to numerous health outcomes including osteoporosis and multiple sclerosis, and more recently type 2 diabetes. Type 2 diabetes is also increasing in prevalence; in the UK an individual is diagnosed with the disease every 3 minutes. Whilst type 2 diabetes does have genetic determinants, it is estimated that nine out of ten cases are attributable to lifestyle choices such as low levels of physical activity and poor diet.

It is widely accepted that physical activity is beneficial for health and being physically active is known to reduce the risk of developing type 2 diabetes. Physical activity can also play a role in the management of the disease by improving blood glucose (sugar) control, insulin sensitivity, and reducing the risk of some of the complications of diabetes. The aim of the current study is to explore the effect of physical activity and vitamin D supplementation on insulin sensitivity and glucose control. Research into the role of vitamin D and physical activity in relation to glucose control and insulin sensitivity will provide guidance in developing lifestyle advice which may reduce the number of people developing type 2 diabetes. It may also help inform treatment for those with pre-existing diabetes and reduce the need for medications in this population. As a healthy individual this research will provide you with information about your vitamin D and fitness levels.

Participation

If you decide to take part in the research study you will be invited to the department of Sport and Exercise Science where you will be randomly allocated to one of four groups (i.e. you have a one in four chance of being allocated into each group). One group will receive a vitamin D supplementation, one group will receive a placebo, one group will have vitamin D supplementation and exercise intervention and one group an exercise intervention and placebo. The study period will last 15 weeks, during the first visit you will fill in some lifestyle questionnaires and have a blood

sample taken. Blood samples will be used to test for glucose, insulin and vitamin D levels. You will also complete a sub-maximal exercise test to estimate fitness level; this will involve cycling at a low to moderate intensity for a short period of time. You will be provided with capsules containing either vitamin D or placebo, you will be asked to come back monthly to collect supplementation/placebo. The exercise groups will be invited to attend 2-3 supervised exercise sessions per week. All groups will be invited back to the department after 15 weeks to repeat the testing procedures carried out during the first visit.

If you decide to take part in the study you would be free to leave the study at any time, without giving prior notification or a reason for doing so.

Risks

With all exercise there are risks, however for the purpose of this study the exercise you will be asked to do will require little effort (i.e. light to moderate intensity), for which the risk is minimal. With all exercise there is an increased risk of cardiac emergency however this is very unlikely in healthy active individuals. To minimise this risk further you will be screened for risk factors using the 'physical activity readiness questionnaire' (PAR-Q).

There is also a small risk of infection and/or bruising after the blood sample being taken. However this risk is small as we carefully follow standard procedures to ensure your safety, and all staff will be fully trained to take blood.

Confidentiality

All information provided or obtained will be treated with utmost confidentiality, and no information that could lead to your identity will be disclosed in any reports on the project, or to any other party. All data collected will be stored securely for an indefinite period of time with a minimum of 6 years for use in research publications; however any data published will be kept anonymous. The data collected may also be used in further research projects and/or by other researchers which have ethical approval.

The information collected during the study will be written up as part of a PhD thesis and as scientific papers. The results gained may be used in other research studies however your personal details will not be published and all data will be anonymous.

Other information

Should you have any further questions regarding participation in the study, I will be pleased to try to answer them, and may be contacted on:

Ffion Curtis

ffc7@aber.ac.uk

01970 622070

Statement of Informed Consent:

I have read the description of the testing procedures involved in this study on the 'The effect of Vitamin D and Physical Activity on health' and I understand what will be required of me as a participant. I have been given the opportunity to ask questions to clarify any aspect of the procedures and I am aware that I have the right to withdraw from the study at any time with no obligation to provide reasons for my decision. I understand that the data collected may also be used in further research projects and/or by other researchers which have ethical approval.

**I agree to take part in the
'The effect of Vitamin D and Physical Activity on Glucose Control' study.**

Signature _____ Date: _____

Name(please print): _____ D.o.B. _____

email _____ phone _____

Witnessed By:

Name (please print): _____ Signature: _____

If you have any queries do not hesitate to ask questions. We can be contacted the Aberystwyth University on tel: 01970 622070 Email: fic@aber.ac.uk
All issues related to indemnity are addressed by Aberystwyth University's insurance cover.

PRIFYSGOL ABERYSTWYTH
ADRAN GWYDDOR CHWARAEON AC YMARFER CORFF
GWYBODAETH I GYFRANOGWYR

Adeilad Carwyn James, Campws Penglais, Prifysgol Aberystwyth, SY23 3FD

Prif Ymchwilydd: Ffion Curtis (fic7@aber.ac.uk; 01970 622070)

Arolygwyr: Dr Rhys Thatcher (ryt@aber.ac.uk; 01970 628 630)

Dr Glen Davison (gdd@aber.ac.uk; 01970 628425)

Teitl yr Astudiaeth: Effaith fitamin D a gweithgaredd corfforol ar reolaeth glwcos

Cefndir

Er ein bod yn cael rhywfaint o fitamin D o'r bwyd yr ydym yn ei fwyta fe'i cawn yn bennaf drwy ddangos ein crwyn i olau'r haul. O ganlyniad i ddiwydiannu a newid yn ein ffordd o fyw, mae prinder fitamin D yn awr yn achos pryder o safbwynt iechyd. Cysylltwyd diffyg fitamin D â nifer o gyflyrau gan gynnwys clefyd esgyrn brau (osteoporosis) a sglerosis ymledol ac, yn fwy diweddar, â chlefyd siwgr math 2. Hefyd, mae clefyd siwgr math 2 ar gynydd; yn y Deyrnas Unedig mae rhywun yn cael ei ddiagnosio gyda'r clefyd bob tri munud. Er bod gan glefyd siwgr math 2 benderfynyddion genynnol, amcangyfrifir bod naw allan o bob deg achos i'w briodoli i ddewisiadau ffordd o fyw, megis lefelau isel o weithgaredd corfforol a diet gwael.

Fe'i derbynir yn gyffredinol bod gweithgaredd corfforol yn llesol i iechyd, a gwyddys hefyd ei fod yn lleihau'r risg o ddatblygu clefyd siwgr math 2. Ar ben hynny, gall gweithgaredd corfforol helpu i reoli'r clefyd drwy wella rheolaeth glwcos (siwgr) yn y gwaed a sensitifrwydd inswlin, yn ogystal â lleihau'r risg o rai o gymhlethdodau'r clefyd. Amcan yr astudiaeth gyfredol yw archwilio effaith gweithgaredd corfforol ac ychwanegiad fitamin D i'r diet ar sensitifrwydd inswlin a rheolaeth glwcos. Bydd ymchwilio i rôl fitamin D a gweithgaredd corfforol mewn perthynas â rheolaeth glwcos a sensitifrwydd inswlin yn ein helpu i roi cyngor ar ffyrdd o fyw a fydd, o bosibl, yn lleihau nifer y bobl sy'n datblygu clefyd siwgr math 2. Mae'n bosibl hefyd y bydd yn cael effaith ar driniaeth y rhai sydd eisoes yn dioddef o glefyd siwgr ac yn lleihau'r angen am foddion yn y boblogaeth honno. Yn achos unigolion iach, bydd yr ymchwil hwn yn darparu gwybodaeth am eu lefelau ffitrwydd a fitamin D.

Cymryd Rhan

Os ydych yn penderfynu cymryd rhan yn yr astudiaeth, cewch eich gwahodd i'r Adran Gwyddor Chwaraeon ac Ymarfer Corff lle byddwch yn cael eich neilltuo, ar hap, i un o bedwar grŵp (h.y. mae gennych un siawns mewn pedwar o gael eich rhoi ym mhob grŵp). Bydd un grŵp yn cael fitamin D atodol, ail grŵp yn derbyn plasebo, trydydd grŵp yn derbyn fitamin D atodol ac yn gorfod ymarfer corff, a'r pedwerydd grŵp yn cael plasebo ac yn gorfod ymarfer corff. Bydd yr astudiaeth yn para am 4 mis ac, yn ystod eich ymweliad cyntaf, byddwch yn gorfod cwblhau holiadur ar eich

ffordd o fyw a rhoi sampl o waed. Bydd samplau gwaed yn cael eu defnyddio i ganfod lefelau glwcos, inswlin a fitamin D yn eich corff. Hefyd, byddwch yn gorfod cwblhau prawf ymarfer corff cymhedrol i ganfod lefel eich ffitrwydd; bydd hyn yn golygu beicio (ar feic ymarfer corff) ar ddwysedd isel/cymhedrol am gyfnod byr o amser. Byddwch yn derbyn tabledi a fydd yn cynnwys fitamin D neu blasebo, a gofynnir ichi ddod nôl bob mis i gael rhagor o atodion/plasebo. Gwahoddir y grwpiau ymarfer corff i ddod i 3 sesiwn ymarfer corff bob wythnos, a hynny dan arolygaeth. Bydd pob grŵp yn cael ei wahodd yn ôl i'r adran ar ôl pedwar mis i ail-wneud y profion a gyflawnwyd yn ystod yr ymweliad cyntaf.

Os ydych yn penderfynu cymryd rhan yn yr astudiaeth, fe fyddwch yn rhydd i roi'r gorau i'r astudiaeth ar unrhyw adeg, a hynny heb roi rhybudd o flaen llaw nac unrhyw reswm.

Risgiau

Mae risgiau ynghlwm wrth unrhyw fath o ymarfer corff. Fodd bynnag, at ddibenion yr astudiaeth hon, bydd yr ymarfer corff y gofynnir i chi ei wneud yn ddigon rhwydd (h.y. dwysedd isel/cymhedrol) ac, o ganlyniad, isel iawn yw'r risg. Gydag ymarfer corff yn gyffredinol, ceir risg uwch o argyfwng cardiaidd, ond mae hynny'n annhebygol iawn yn achos pobl iach, fywiog. I leihau'r risg ymhellach, byddwch yn cael eich sgrinio ar gyfer ffactorau risg drwy ddefnyddio'r holiadur 'parodrwydd ar gyfer gweithgaredd corfforol'. (PAR-Q).

Ar ben hyn, mae risg bychan o heintio a/neu gleisio ar ôl cymryd gwaed. Er hynny, y mae'r risg yma'n fychan gan ein bod yn dilyn trefnau safonol yn ofalus i sicrhau eich diogelwch, a bydd y staff wedi eu hyfforddi'n llawn i dynnu gwaed.

Cyfrinachedd

Bydd yr holl wybodaeth a ddarperir neu a dderbynnir yn cael ei thrin yn gwbl gyfrinachol, ac ni fydd unrhyw wybodaeth a allai ddatgelu pwy ydych yn cael ei dadlennu mewn unrhyw adroddiadau ar y prosiect, nac ychwaith i unrhyw berson arall. Bydd yr holl ddata a gesglir yn cael ei gadw'n ddiogel am gyfnod amhenodol, gyda lleiafswm o chwe blynedd cyn y ceir ei ddefnyddio mewn cyhoeddiadau ymchwil; fodd bynnag, bydd unrhyw ddata a gyhoeddir yn cael ei gadw'n ddiennw. Ar ben hynny, mae'n bosibl y bydd y data a gesglir yn cael ei ddefnyddio mewn prosiectau ymchwil pellach a/neu gan ymchwilwyr eraill sydd wedi cael sêl bendith foesegol i wneud hynny.

Bydd yr wybodaeth a gesglir yn ystod yr astudiaeth yn cael ei chynnwys mewn traethawd PhD a'i chyflwyno mewn papurau gwyddonol. Dichon y bydd y canlyniadau'n cael eu defnyddio mewn astudiaethau ymchwil eraill. Serch hynny, ni chyhoeddir eich manylion personol, a bydd yr holl ddata yn anhysbys.

Gwybodaeth bellach

Os oes gennych unrhyw gwestiynau pellach ynglŷn â chymryd rhan yn yr astudiaeth, y mae croeso i chi gysylltu â mi:

Datganiad o Gydsyniad Gwybodus:

Rwyf wedi darllen y disgrifiad o'r dulliau profi a oblygir gan yr astudiaeth hon ar 'Rôl fitamin D a gweithgaredd corfforol yn achos clefyd siwgr math 2', ac rwyf yn deall beth a ddisgwylir gennyf fel cyfranogwr. Rhoddwyd cyfle i mi ofyn cwestiynau i egluro unrhyw agwedd ar y dulliau gweithredu ac rwyf yn ymwybodol fod gennyf yr hawl i dynnu'n ôl o'r astudiaeth ar unrhyw adeg heb unrhyw orfodaeth i roi rhesymau dros fy mhenderfyniad.

Rwy'n cytuno i gymryd rhan yn yr astudiaeth ar
'Rôl fitamin D a gweithgaredd corfforol yn achos clefyd siwgr math 2'

Enw (llythrennau bras): _____ Dyddiad: _____

Llofnod: _____ Dyddiad geni: _____

Ardystiwyd gan:

Enw (llythrennau bras): _____ Llofnod: _____

Os oes gennych unrhyw gwestiynau, cysylltwch â ni ym Mhrifysgol Aberystwyth ar:
01970 622070, E-bost: fic@aber.ac.uk

Appendix 2

Sun Exposure Questionnaire (Hanwell et al., 2010)

Please think back over the last week and put an X in one of the boxes for 'time outdoors' and another X in one of the boxes for 'amount of skin exposed'. Please do this for each of the seven days of the week.

	Time Outdoors			Amount of Skin Exposed			
	<5 min	5-30 min	>30 min	Hands and face	Hands, Face, arms	Hands, face, legs	Bathing suit
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
Sunday							

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRES

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

IPAQ: SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken in 12 countries (14 sites) across 6 continents during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages. IPAQ is suitable for use in regional, national and international monitoring and surveillance systems and for use in research projects and public health program planning and evaluation. International collaboration on IPAQ is on-going and an international prevalence study is under development.

Using IPAQ

Worldwide use of the IPAQ instruments for monitoring and research purposes is encouraged.

It is strongly recommended, to ensure data quality and comparability and to facilitate the development of an international database on health-related physical activity, that

- no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments,
- if additional questions on physical activity are needed they should follow the IPAQ items,
- translations are undertaken using the prescribed back translation methods (see website)
- new translated versions of IPAQ be made available to others via the web site to avoid duplication of effort and different versions in the same language,
- a copy of IPAQ data from representative samples at national, state or regional level be provided to the IPAQ data storage center for future collaborative use (with permission) by those who contribute.

More Information

Two scientific publications presenting the methods and the pooled results from the IPAQ reliability and validity study are due out in 2002.

More detailed information on the IPAQ process, the research methods used in the development of the IPAQ instruments, the use of IPAQ, the published papers and abstracts and the on-going international collaboration is available on the IPAQ web-site.

**INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE
IPAQ: SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT
FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS**

NOTE: EXAMPLES OF ACTIVITIES MAY BE REPLACED BY CULTURALLY RELEVANT

EXAMPLES WITH THE SAME METS VALUES (SEE AINSWORTH *ET AL.*, 2000).

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

**INTERNATIONAL PHYSICAL ACTIVITY
QUESTIONNAIRE**

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. This is part of a large study being conducted in many countries around the world. Your answers will help us to understand how active we are compared with people in other countries.

The questions are about the time you spent being physically active in the last 7 days. They include questions about activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Your answers are important.

Please answer each question even if you do not consider yourself to be an active person.

THANK YOU FOR PARTICIPATING.

In answering the following questions,

- ◆ vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal.
- ◆ moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

This is the final SHORT LAST 7 DAYS SELF-ADMINISTERED version of IPAQ from the 2000/01 Reliability and Validity Study. Completed May 2001.

1a. During the last 7 days, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling,?
Think about *only* those physical activities that you did for at least 10 minutes at a time.

_____ days per week ⇨ or none

2a. Again, think *only* about those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week or none

3a. During the last 7 days, on how many days did you **walk** for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.

_____ **days per week** ⇨ **or none**

The last question is about the time you spent sitting on weekdays while at work, at home, while doing course work and during leisure time. This includes time spent sitting at a desk, visiting friends, reading traveling on a bus or sitting or lying down to watch television.

4. During the last 7 days, how much time in total did you usually spend *sitting* on a week day? _____ hours _____ minutes

This is the end of questionnaire, thank you for participating.